# NOV 8 2005

Andrew Pechko AVON Products Inc. 1251 Avenue Of The Americas New York, NY 10020-1196

Subject: Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent EPA Registration No. 806-29
E-mail dated September 29, 2005
Letter dated October 12, 2005

Dear Mr. Pechko:

The proposed amendment to the registration of the product cited above under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, revising the label by adding claims for efficacy against mosquitoes that may carry(transmit) West Nile Virus is acceptable subject to the comments listed below:

1) The claim repels mosquitoes that may carry(transmit) West Nile Virus is acceptable. However, the data support a only 4 hour repellency claim. The duration claims for mosquitoes must be changed to 4 hours. As a condition of acceptance of this claim, Avon must agree to submit formulation specific confirmatory efficacy data meeting the the 810.3800 product performance guidelines within one year of the release of said guidance.

Alternatively, if you wish to claim 6 hours protection against mosquitoes, **no** reference to West Nile Virus can be made.

- 2) Delete the term, long lasting wherever it appears or qualify it with the duration times supported by data.
- 3) Delete the statement, "An adult must handle and apply this product to children under 10.", and add the statements, "Do not allow children to handle this product. When applying on children, apply to your own hands and then put it on the child".
- 4) The claim for use on clothing is being accepted under the following conditions:

Data must be submitted to support the efficacy of the product when applied to clothing. A

protocol for running the study must be submitted. Once the protocol has been approved, the data must be submitted within one year or you must delete the claim by submitting a label amendment to that effect. You must agree to these conditions.

5) Any additional marketing claims must be submitted as amendments.

The proposed alternate brand names are acceptable

A copy of the Efficacy review is enclosed.

A stamped copy of the draft label is enclosed. Submit two (2) copies of the revised final printed label along with your commitment to the requirements stated in comment number 4.

If you have any questions please contact Joseph Tavano at (703) 305-6411.

Sincerely,

:

Richard Gebken

Product Manager 10

Insecticide Branch

Registration Division (7505C)

10/03/05 1 of 3

# [Bracketed and parenthetical text is additional product information, which may or may not appear on final product label]

#### FRONT OF CONTAINER:

AVON

SKIN-SO-SOFT

S

S

S

**BUG GUARD PLUS** 

**PICARIDIN** 

INSECT REPELLENT

ACCEPTED
with COMMENTS
In EPA Letter Dated:

NOV 8 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amonded, for the pesticide registered under EPA Reg. No.

### [ALTERNATE BRAND NAME #1:]

**AVON** 

SKIN-SO-SOFT

S

S

S

**PICARIDIN** 

**INSECT REPELLENT** 

#### [ALTERNATE BRAND NAME#2:]

**AVON** 

**BUG GUARD PLUS** 

**PICARIDIN** 

INSECT REPELLENT

[Strong and long-lasting repellency against mosquitoes, deer ticks, black flies, gnats, no-seeums, sand flies and biting midges]

[Strong and long-lasting repellency against mosquitoes and deer ticks]

[Repels mosquitoes up to 6 hours and deer ticks up to 7 hours]

[Repels mosquitoes up to 6 hours]

[Repels deer ticks up to 7 hours]

[Repels mosquitoes that may (carry) (transmit) West Nile Virus up to 6 hours]

[Repels mosquitoes that may (carry) (transmit) West Nile Virus]

[Repels deer ticks that may (carry) (transmit) Lyme Disease up to 7 hours]

[Repels deer ticks that may (carry) (transmit) Lyme Disease]

OUTDOOR COOL™ SCENT

[with vitamin E]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements

**ACTIVE INGREDIENT:** 

Picaridin[\*]

10.0%

OTHER INGREDIENTS:

90.0%

TOTAL:

100.0%

[\*Bayrepel™]

[Bracketed and parenthetical text is additional product information, which may or may not appear on final product label]

#### **BACK OF CONTAINER:**

<u>REPELLENCY</u> — [Avon's exclusive formula (with Picaridin) (with Bayrepel™) repels (insects) (mosquitoes and deer ticks) that may (carry) (transmit) West Nile Virus and Lyme Disease.] [Patented technology that] Provides [strong and] [dependable and] long-lasting repellency against mosquitoes, deer ticks, black flies, gnats, no-seeums, sand flies and biting midges. Works on clothing too!

<u>SUITABLE FOR THE ENTIRE FAMILY</u> – [Pleasantly scented.] [Non-oily spray.] [Light feel.] [Non-greasy spray.] [Pleasantly scented, (non-oily) (non-greasy) (light feeling) spray.] Provides the whole family with an effective broad-spectrum outdoor (bug) (insect) repellent. [Contains Vitamin E.]

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label. Hold container 6 to 8 inches from skin or clothing and spray with a slow sweeping motion liberally and evenly. Do not spray in enclosed areas. Do not apply under clothing, on cuts, wounds, freshly shaved, excessively sunburned or irritated skin. TO APPLY TO FACE: Spray palm of hand and rub on, avoiding the eye and lip area. Use sparingly around ears. Use just enough repellent to cover exposed skin. Avoid over application of product. An adult must handle and apply this product to children under 10. Do not apply directly to children's hands. FOR CONTINUED PROTECTION from deer ticks, gnats, no-seeums, sand flies and biting midges reapply after 7 hours; for mosquitoes reapply after 6 hours; for black flies reapply after 3 hours. Do not exceed 2 applications per day.

STORAGE: Store in cool, dry place away from heat or flame.

treatment information.

DISPOSAL: Do Not Puncture or Incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

PRECAUTIONARY STATEMENTS: Hazards to Humans. Caution: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes and do not spray on face. Wash thoroughly with soap and water after handling, returning indoors, and before eating, drinking, chewing gum, or using tobacco. Wash treated clothing before wearing again. Discontinue use and consult a doctor if irritation or rash occurs.

FIRST AID	
If in eyes:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	Call a poison control center or doctor for treatment advice.
If	Call a poison control center or doctor immediately for treatment advice.
swallowed	Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to by a poison control center or doctor.
	Do not give anything to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor,	
or going for treatment. You may also contact 1-800-FOR-AVON for emergency medical	

PHYSICAL HAZARDS - FLAMMABLE: Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Keep treated surface away from fire or flame until dry. [Intentional misuse by deliberately concentrating and inhaling contents may be harmful or fatal.]

DRAFT MASTER LABEL FOR EPA REG. NO. 806-29

10/03/05 AVON SKIN-SO-SOFT SSS BUG GUARD PLUS PICARIDIN INSECT REPELLENT AEROSOL SPRAY 3 of 3

## [Bracketed and parenthetical text is additional product information, which may or may not appear on final product label]

BACK OF CONTAINER- continued:

[Will not harm most plastics or synthetic fabrics.] [May damage painted or varnished surfaces(, including nail polish).]

To order, see an Avon Representative, or call 1-800-FOR-AVON. www.avon.com [Not for sale or use after expiration date.] [Bayrepel™ is a trademark of (Bayer Corporation) (Lanxess)] EPA Reg. No. 806-29 EPA Est. No. [013891-IN-001] [054487-GA-001] [33590-MA-003] AVON PRODUCTS, INC., DISTR. 1251 AVE. OF THE AMERICAS, NY, NY 10020 AVON 200X – ALL RIGHTS RESERVED [U.S. Patent No. 6,719,959 and other patents pending]

> **Bottom of Container:** Julian Day Lot Code Number Exp. Month/ Year